DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0389]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reprocessed Single-Use Device Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on reprocessed single-use device labeling.

DATES: Submit written or electronic comments on the collection of information by November 28, 2005.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reprocessed Single-Use Device Labeling (21 U.S.C. 352(u))

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amended section 502 of the act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109–43) amends section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. MDUFSA was enacted on August 1, 2005, and becomes self-implementing on August 1, 2006.

The requirements of section 502(u) of the act impose a minimal burden on industry. This section of the act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 3 establishments that distribute approximately 300 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 30 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the act	No. of Respondents	Annual Responses Per Respondent	Total Annual Responses	Hours per Response	Total Hours
502(u)	3	100	300	0.1	30

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19509 Filed 9–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0161] (formerly Docket No. 03N–0161)

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is adding noncompression heart stabilizers to the list of critical reprocessed single-use devices (SUDs) whose exemption from premarket notification requirements has been terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), are necessary in a premarket notification (510(k)). The agency is also adding laparoscopic and endoscopic electrosurgical accessories to the list of reprocessed SUDs currently subject to premarket notification requirements that will now require submission of supplemental validation data. FDA is requiring submission of these data to ensure that reprocessed single-use noncompression heart stabilizers and laparoscopic and endoscopic electrosurgical accessories are substantially equivalent to predicate devices, in accordance with MDUFMA.

DATES: These actions are effective September 29, 2005. Manufacturers of reprocessed single-use noncompression heart stabilizers must submit 510(k)s for these devices by December 29, 2006, or their devices may no longer be legally marketed. Manufacturers of reprocessed single-use laparoscopic and endoscopic electrosurgical accessories who already have 510(k) clearance for these devices must submit supplemental validation data for the devices by June 29, 2006, or their devices may no longer be legally marketed.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara A. Zimmerman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 158.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Public Law 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, in order to ensure that reprocessed SUDs are substantially equivalent to predicate devices, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data. These required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs are no longer exempt from premarket notification requirements. Manufacturers of these identified devices were required to submit 510(k)s that included validation data specified by FDA. Reprocessors of certain SUDs already subject to cleared 510(k)s were also required to submit the validation data specified by the agency.

The reprocessed SUDs subject to these new requirements were listed in the **Federal Register** as required by MDUFMA. In accordance with section 510(o) of the act, FDA shall revise the lists as appropriate. This notice adds two types of reprocessed SUDs to the lists of devices subject to MDUFMA's data submission requirements. Noncompression heart stabilizers are being added to the list of previously exempt reprocessed SUDs that now require the submission of 510(k)s containing validation data. Laparoscopic and endoscopic electrosurgical accessories are being added to the list of reprocessed SUDs, already subject to premarket notification requirements, for which supplemental validation data are required.

A. Definitions

Under section 302(b) of MDUFMA, a reprocessed SUD is defined as an ''original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.''

Reprocessed SUDs are divided into three groups: (1) critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions set forth in MDUFMA, and all three reflect a classification scheme recognized in the industry.[1] These categories of devices are defined as follows:

(1) *A critical reprocessed SUD* is intended to contact normally sterile tissue or body spaces during use.

(2) *A semicritical reprocessed SUD* is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(3) *A noncritical reprocessed SUD* is intended to make topical contact and not penetrate intact skin.

B. Critical and Semicritical Reprocessed SUDs Previously Exempt From Premarket Notification

MDUFMA required FDA to review the critical and semicritical reprocessed SUDs that were previously exempt from premarket notification requirements and determine which of these devices required premarket notification to ensure their substantial equivalence to predicate devices. By April 26, 2003, FDA was required to identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). According to the law, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87 (21 CFR 807.87), within 15 months of

[1]Spaulding, E.H., ''The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections,'' P.S. Brachman and T.C. Eickof (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 254-274, 1971.